

## REMARKS

### Rejections of Claims and Traversal Thereof

In the September 22, 2006 Office Action:

claims 1-3, 5-9, 10-12, 14-18, 19-21, 23-27, 28-30, 32-36 and 58 were rejected under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Buncke (U. S. Patent No. 5,931,855);

claims 4, 13, 22 and 31 were rejected under 35 U.S.C. §103(a) as obvious over Buncke (U. S. Patent No. 5,931,855) and further in view of Buncke (U. S. Patent No. 5,931,855) [sic];

claims 115-140 were rejected under 35 U.S.C. §103(a) as obvious over Buncke (U. S. Patent No. 5,931,855) and further in view of Ruff, et al. (U.S. Patent No. 5,342,376); and

claims 58 and 60 were rejected on the grounds of judicially created nonstatutory obviousness-type double patenting as being unpatentable over claim 16 and 22, respectively, of copending Application No. 10/065280.

These rejections are hereby traversed, and reconsideration of the patentability of the pending claims herein is requested, in light of the ensuing remarks.

### Rejections under 35 U.S.C. §102(b)/ 35 U.S.C. §103(a)

Claims 1-3, 5-9, 10-12, 14-18, 19-21, 23-27, 28-30, 32-36 and 58 were rejected under 35 U.S.C. §102(b) as being anticipated by or in the alternative, under 35 U.S.C. §103(a) as obvious over Buncke (U. S. Patent No. 5,931,855). Applicants submit that the Buncke reference does not anticipate or render obvious the presently claimed invention.

1. Claim 1 of the present invention recites the following:

1. A barbed suture for connecting human or animal tissue, said suture comprising (a) an elongated body having a first end and a second end and (b) a plurality of barbs projecting from the body, each barb facing in a direction and being adapted for resisting

movement of the suture, when in tissue, in an opposite direction from the direction in which the barb faces, wherein the barbs have a configuration comprising a barb cut angle  $\Theta$  ranging from about 140 degrees to about 175 degrees.

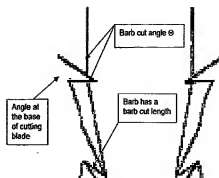
Importantly, the present invention as recited in claim 1 describes barbs having a barb cut angle  $\Theta$  ranging from about 140 degrees to about 175 degrees.

As stated and recognized by the Office,

"Buncke reference fails to disclose the barb cut angle ranging from about 140 degrees to about 175 degrees, however, what is abundantly clear from Figure 15 of Buncke drawings is that the cutting blade has a sharp cutting edge, a base and an angle (see Figure below paragraph 5) whereby said angle of the cutting blade creates the barb cut angle on the suture . . . Here it is noted that it has been held that things clearly shown in reference patent drawing qualify as prior art features, even though unexplained by the specification. In re Mraz, 173 USPQ 25 (CCPA 1972)."

Applicants vigorously disagree that the Buncke reference and any figures therein show a barb cut angle  $\theta$ , from about 140 degree to 175 degree. The Office's citing of *In re Mraz* is not relevant in the present situation because the specific Figure 3, discussed by the *Mraz* Court, was not a patent drawing per se, but instead, Figure 3, "was on a greatly enlarged section of a smaller drawing. . ." Thus, because Figure 3 was a greatly enlarged and detailed view of a smaller section shown in Figure 1, the *Mraz* Court determined there was sufficient disclosure without additional description in the specification.

However, Figure 15 from Buncke, and discussed by the Office, is not an enlarged sectional view and provides very little detail. As such, the case law cited by the Office does not pertain to the present situation. Interestingly, the Office created its own enlarged view of a section of Figure 15 (Page 4 of the September 30, 2006 Office Action) but the Office's illustration does not remedy the shortcomings of Buncke's Figure 15. Although the enlarged section, created by the Office and set forth below, is very nice, the *Mraz* Court stated that this enlarged figure had to be in the prior art reference and not created by the Patent Office.



Thus, the Office's attempt to show an enlarged sectional view does not meet the requirements set forth by the *Mraz* Court.

Applicants submit that it is well settled in the law that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue. See *In re Wright* 193 USPQ 332 (CCPA 1977). Further, in 2005 the Federal Circuit reiterated this ruling and stated that "arguments based on drawings that are not explicitly made to scale are unavailing." As stated by the *Nystrom* Court, "absent any written description in the specification of quantitative values, arguments bases on measurement of a drawing are of little value." See *Nystrom v TREX Co*, 76 USPQ2d 1481 (Fed. Cir. 2005). Applicants reviewed the entire Buncke reference and found no text that stated that the drawings were to scale.

Further, section 2125 of the MPEP agrees with the *Nystrom* Court and states that:

"When the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value. See *Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 222 F.3d 951, 956, 55 USPQ2d 1487, 1491 (Fed. Cir. 2000) (The disclosure gave no indication that the drawings were drawn to scale. "[I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue.").

As stated above, the Buncke reference is completely devoid of any description relating to the barb angles and the drawings alone cannot be relied on because the drawings are devoid of specific information.

The Office states that the enlarged sectional drawing, notably created by the Office "clearly shows the barb cut angle  $\theta$ , definitely, ranging from about greater than 0 degree to less than 180 degree, possibly, ranging from about 135 to less than 180 degree." Interestingly, the fact that the Office used the word "possibly" introduces a considerable level of uncertainty. For a reference to be considered anticipatory, the anticipatory elements have to be present each and every time. Importantly, the fact that the Office suggests that the angle may "possibly" be between 135 to less than 180 degree emphasizes the fact that the angle may not be included in applicants' range. Thus, the Office has been reduced to mere speculation because the Buncke reference is completely devoid of any discussion relating the barb angles.

According to the Office:

It would have been an [sic] obvious to a person of ordinary skill in art [sic] to derive the barb cut angle from the depth and spacings parameters given by Buncke , since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.”

Thus, the Office’s position in essence is that applicants have done nothing more than use routine experimentation to optimize the system. However, conspicuously missing from the record is any substantive evidence that one of ordinary skill in the art would have been motivated to make the modifications of the prior art and select the specific angle ranges to arrive at applicants’ claimed invention. Further, the Office has neglected to show any teaching or suggestion as to why one would choose applicants’ claimed angle ranges. The Office’s argument that “routine operation” was involved in determining the optimal angle range for the barbs shows that the Office overlooked the last sentence of 35 USC §103, which states that “[p]atentability shall not be negated by the manner in which the invention was made.” *In re Fay*, 146 USPQ 47 (CCPA 1965).

To establish a *prima facie* case of obviousness, the Office must show some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference; there must be a reasonable expectation of success; and the prior art reference must teach or suggest all the claim limitations. See, MPEP §2142. Notably, the teaching or suggestion to make the claimed modification and the reasonable expectation of success must both be found in the prior art, and not based on the applicant’s disclosure. *In re Vaack*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

Applicants contend that the enlarged rendition of Buncke’s Figure 15, **not found in Buncke but instead created by the Office**, without any additional guidance is not sufficient to meet the Office’s burden of establishing a *prima facie* case of obviousness. The speculation by the Office amounts to an “obvious to try” rejection and using the “obvious to try” test would often deny patent protection to inventions growing out of well-planned research which is, of course, guided into those areas in which success is deemed most likely. These are, perhaps, the obvious areas to try. **But resulting inventions are not necessarily obvious.** Serendipity is not a prerequisite to patentability. *In re Lindell*, 155 USPQ 521, 523 (C.C.P.A. 1967).

Applicants insist that the Office **has not established a *prima facie* case of obviousness**, and due to this lack of showing of obviousness, applicants do not need to submit evidence of unexpected results as a form of rebuttal. Interestingly, the Buncke reference does not include any defined barb angles, and as such, how could the present applicants make any type of comparisons of the presently claimed invention with that of Buncke. Applicants should have some guidance regarding what angle is taught in Buncke and it is very clear there is no guidance in Buncke relating to any barb angles. Applicants insist that claims reciting the barb angle from 140 to 175 are not anticipated or rendered obvious by the Buncke reference.

2. According to the Office, independent claims 10, 19 and 28 and all claims depending therefrom are obvious in light of Buncke. Again applicants respectfully disagree with the Office.

Specifically, the presently claimed invention recited in independent claims 10, 19 and 28 include a barbed suture for connecting human or animal tissue, comprising

- (a) an elongated body having a first end and a second end and a diameter; and
- (b) a plurality of barbs projecting from the body, each barb facing in a direction and being adapted for resisting movement of the suture, when in tissue, in an opposite direction from the direction in which the barb faces, wherein the barbs have a configuration comprising at least one of the following:
  - (i) a barb cut depth where the **ratio of the barb cut depth to the suture diameter ranges from about 0.05 to about 0.6** (claim 10),
  - (ii) a barb cut length where the **ratio of the barb cut length to the suture diameter ranges from about 0.2 to about 2** (claim 19), or
  - (iii) a barb cut distance where the **ratio of the barb cut distance to the suture diameter ranges from about 0.1 to about 6** (claim 28).

Thus, claim 10 of the presently claimed invention recites a **ratio (D:SD)** of the barb cut depth (D) to the suture diameter (SD) wherein the ratio is from about 0.05 to about 0.6; claim 19 recites a **ratio (L:SD)** of the barb cut length (L) to the suture diameter (SD) wherein the ratio is from about 0.2 to about 2; and claim 28 recites a barb suture comprising a barb cut distance (**P:SD**) with ratio of the barb cut distance (P) to the suture diameter (SD) that ranges from about 0.1 to about 6.

The Office admits that "Buncke reference fails to disclose the barb cut length and the ratio of the barb cut length to suture diameter ranging from about 0.2 to about 2." Applicants agree that the Buncke reference is **completely devoid of any mention of a ratio** and the Office has not shown any disclosure, teaching or suggestion of such mathematical calculations to show that ratios were even considered by Buncke. To determine a ratio, there has to be a mathematical manipulation of data wherein a numerator is divided by a denominator. Thus one has to determine the numerator and the denominator to perform the necessary calculations. Applicants insist that the Buncke reference does not provide any teaching or guidance relating to what values will be included in the calculations and how they are to be mathematically manipulated.

Instead, the only values included in the Buncke reference describe barbed sutures having suture diameter ranging from 100 microns to 500 microns, the spacing of the barbs from 100 microns to 1 mm, and the depth of the barb cut in the suture ranging from 30 micron to 100 microns. (See Buncke at column 8, lines 14-19).

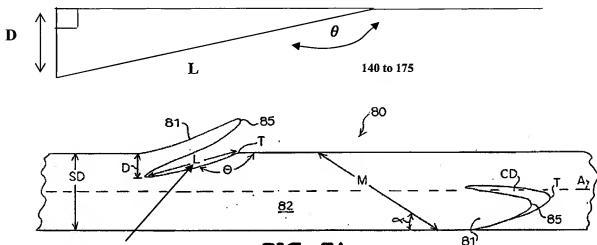
As shown in the set forth table below, there are only three Buncke parameters but none of these parameters are included in a specific ratio range and there is no guidance as to which parameter is acceptable as a numerator or denominator to calculate a ratio. Clearly, the determination of the numerator and denominator will have a great impact on the resultant ratio and the Buncke reference provides no such guidance.

Parameter	Numerical Value
Suture Diameter	100 microns to 500 microns
Spacing of the barbs	100 microns to 1 mm,
Depth of the barb cut	30 micron to 100 microns

Further, it should be recognized that the Buncke reference does not provide sufficient information to determine the (L:SD) ratio (as required by Claim 28) because the Buncke reference does not include any indication of a barb angle and without such an angle the barb length cut (L) cannot be measured.

Simple highschool geometry shows that an angle is required to determine the barb length cut as shown below.

$\sin \theta = \text{opp/hyp}$



**FIG. 7A**

There is nothing in Buncke, to provide any guidance for mathematically determining the value of the barb cut length (L), as shown in applicants' Figure 7A recreated above, because the Buncke reference does not disclose, teach or suggest an angle of slicing into the suture.

Clearly, there is nothing in the Buncke reference that teaches the presently claimed ratios and Office cannot conjure this up or speculate by relying on something that is not disclosed. The Court's decision in *In re Spormann*, 150 USPQ 449 (CCPA 1966), bears directly on point:

"Obviousness cannot be predicated on what is unknown"

Hence, obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established. *In re Rijckaert*, 28 USPQ2d 1955 (Fed. Cir. 1993). Heretofore the ratios set forth in applicants' claimed invention were unknown. Therefore, how could a skilled artisan make any modification of Buncke while arriving at an invention that possesses the heretofore unknown characteristic. While it is possible that, serendipitously, the invention would have such a feature, serendipity is not a valid basis for asserting obviousness. It is evident that the Office is relying on a hindsight reconstruction of the prior art to arrive at the present invention. Thus, this allegedly "obvious" modification is supported only by the Office's reinterpretation of the art in light of applicants' disclosure.

Importantly, the wide ranges disclosed by Buncke for suture diameter, barb depth cut and distance between barbs provides no guidance as to what type of mathematical manipulation is necessary. Moreover, even if ratios were disclosed by Buncke, **which of course they are not**, and assuming that one skilled in the art would correctly guess as to the numerator and denominator, the ratio ranges would be so extensive and cover such a large area, that no reasonable fact finder could conclude that the Buncke reference describes applicants' claimed range or disclose the end points of the range with sufficient specificity to anticipate or render obvious applicants' claimed invention. See *Atofina v. Great Lakes Chemical Corp*, 78 USPQ2d 1417 (Fed Cir. 2006).

Again, the Office repeatedly discusses the need for proof of unexpected results. However, it is well settled in the law that unexpected results are not required to be shown until the Office has an established a *prima facie* case of obviousness. To date this burden has not been met because all elements of the presently claimed invention have not been disclosed, Buncke provides no motivation to modify the Buncke reference to go in the direction of applicants' claimed invention and provides no direction for such modification. There is no hope of success for this modification when Buncke offers no instructions for such modification.

In light of the above discussion, the Office has failed to establish a *prima facie* case of obviousness and applicants request the withdrawal of the rejections of claims 1-3, 5-12, 14-21, 23-30, 32-36 and 58 under both 35 U.S.C. §102(b) and §103(a).

#### **Rejection under 35 U.S.C. §103(a)**

Claims 4, 13, 22 and 31 were rejected under 35 U.S.C. §103(a) as obvious over Buncke (U. S. Patent No. 5,931,855) and further in view of Buncke (U. S. Patent No. 5,931,855). This combination cannot be correct and applicants suspect that the Office instead meant to include Leung, et al. (U.S. Patent No. 6,599,310).

However, as stated in the previous response, the proposed combination of Buncke and Leung, et al is not a proper combination of references because under 35 USC §103(c), subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title shall not preclude patentability under this section [section 103 obviousness rejections] where the subject matter and the claimed invention were, at



the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

At the time that the presently claimed invention was made, it and the '310 patent to Leung et al. were owned by and also subject to an obligation of assignment to the same person, Quill Medical, Inc. Notably, Leung, et al was filed on June 29, 2001 and issued on July 29, 2003 and as such qualifies as a 102 (e) reference. Accordingly, this statement by the undersigned attorney is sufficient to remove Leung, et al. as competent prior art, and thus, this proposed combination of references does not meet the requirements to establish a *prima facie* case of obviousness.

Accordingly, the Office is respectfully requested to remove the obviousness rejection based on Buncke in view of Leung et al.

Claims 115-140 were rejected under 35 U.S.C. §103(a) as obvious over Buncke (U. S. Patent No. 5,931,855) and further in view of Ruff, et al. (U.S. Patent No. 5,342,376). According to the Office:

“Buncke discloses the invention substantially as claimed except for the cross section of suture body has a circular or non-circular cross section.”

Applicants insist that Buncke does not disclose, teach or suggest the presently claimed invention and introducing the teachings of Ruff does not cure the shortcomings of Buncke. Again, as stated numerous times, the Buncke reference does not disclose all elements of the presently claimed invention, provides no motivation to modify the Buncke sutures and provides no direction for such modification. As such, the proposed combination by the Office does not meet the standards of establishing a *prima facie* case of obviousness and applicants request the withdrawal of this rejection under 35 USC §103(a).

#### **Rejection under Judicially Created Doctrine of Obviousness-Type Double Patenting**

Claims 58 and 60 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16 and 22, respectively, of copending application No. 10/065,280. Applicants traverse this double patenting rejection. In any case, until the only remaining rejection is the obvious-type double patenting, applicants will delay filing a terminal disclaimer.

### **Fees Payable**

No fees are due for entry of this amendment, however, if a fee is found due, the U.S. Patent and Trademark Office is hereby authorized to charge such fee to Deposit Account No. 13-4365 of Moore & Van Allen, PLLC.

### **Conclusion**

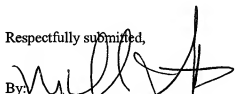
Applicants have satisfied the requirements for patentability. All pending claims are free of the art and fully comply with the requirements of 35 U.S.C. §112. It therefore is requested that Examiner Nguyen, reconsider the patentability of all pending claims, in light of the distinguishing remarks herein and withdraw all rejections, thereby placing the application in condition for allowance. Notice of the same is earnestly solicited. In the event that any issues remain, Examiner Nguyen is requested to contact the undersigned attorney at (919) 286-8089 to resolve same.

Date:

3-22-07

Respectfully submitted,

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